

Amendment No. 2 to SB2253

Crowe
Signature of Sponsor

AMEND Senate Bill No. 2253

House Bill No. 2391*

by deleting all language after the enacting clause and by substituting instead the following:

SECTION 1. This act shall be known and may be cited as the "Tennessee Prescription Safety Act of 2012."

SECTION 2. Tennessee Code Annotated, Section 53-10-302, is amended by deleting the section in its entirety and by substituting instead the following:

53-10-302.

As used in this part:

- (1) "Board" means the board of pharmacy created by title 63, chapter 10, part 3;
- (2) "Commissioner" means the commissioner of health;
- (3) "Committee" means the controlled substance database committee created by this part;
- (4) "Controlled substances" means a drug, substance or immediate precursor in Schedules I through VI defined or listed in title 39, chapter 17, part 4;
- (5) "Database" means the controlled substance database created by this part;
- (6) "Department" means the department of health;
- (7) "Dispense" means to physically deliver a controlled substance covered by this part to any person, institution or entity with the intent that it be consumed away from the premises on which it is dispensed. It does not include the act of writing a prescription by a practitioner to be filled at a pharmacy licensed by the board. For purposes of this act, physical delivery includes mailing controlled substances into this state;
- (8) "Dispenser" means a pharmacist, a pharmacy, or any health care practitioner who is licensed and has current authority to dispense controlled substances;

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(9) "Health care practitioner" means:

(A) A physician, dentist, optometrist, veterinarian, or other person licensed, registered, or otherwise permitted to prescribe, distribute, dispense or administer a controlled substance in the course of professional practice; or

(B) A pharmacy, hospital or other institution licensed, registered, or otherwise permitted to distribute, dispense, or administer a controlled substance in the course of professional practice;

(10) "Health care practitioner extender" means any registered or licensed health care professional, and up to two (2) unlicensed persons designated by the prescriber or dispenser, who act as agents of that prescriber or dispenser. The prescriber or dispenser shall be responsible for all actions taken by their agents pursuant to this act.

(11) "Law enforcement personnel" means agents of the Tennessee bureau of investigation, agents of a judicial district drug task force, federal law enforcement officers commissioned by a federal government entity, certified law enforcement officers certified pursuant to §38-8-107, and certified law enforcement officers in other states; and

(12) "Prescriber" means an individual licensed as a medical doctor, podiatrist, dentist, optometrist, veterinarian, osteopathic physician, or physician assistant who has the authority to issue prescriptions for controlled substances, or an advanced practice nurse with a certificate of fitness to prescribe and the required supervisory relationship with a physician.

SECTION 3. Tennessee Code Annotated, Section 53-10-303(a), is amended by deleting the word "advisory".

SECTION 4. Tennessee Code Annotated, Section 53-10-303(f), is amended by deleting the subsection in its entirety and substituting instead the following:

(f) The commissioner shall have the authority to promulgate rules and regulations, pursuant to the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, necessary for implementation of this part. The commissioner shall promulgate rules regarding:

- (1) Establishing, maintaining and operating the database;
- (2) Access to the database and how access is obtained;
- (3) Control and dissemination of data and information in the database;

and

- (4) The sharing and dissemination of data and information in the database with other states or other entities acting on behalf of a state.

SECTION 5. Tennessee Code Annotated, Section 53-10-304(d), is amended by deleting the subsection in its entirety and substituting instead the following:

(d) The data required by this part shall be submitted in compliance with this part to the database by any dispenser, or dispenser's agent, who dispenses a controlled substance contained in Schedules II, III, and IV, and Schedule V controlled substances identified by the controlled substance database committee as demonstrating a potential for abuse. The reporting requirement shall not apply for the following:

- (1) A drug administered directly to a patient;
- (2) Any drug sample dispensed;
- (3) Any drug dispensed by a licensed veterinarian; provided, that the quantity dispensed is limited to an amount adequate to treat the non-human patient for a maximum of forty-eight (48) hours;
- (4) Any facility that is registered by the United States drug enforcement administration as a narcotic treatment program and is subject to the recordkeeping provisions of 21 CFR 1304.24; or

(5) Any drug dispensed by a licensed health care facility; provided, that the quantity dispensed is limited to an amount that is adequate to treat the patient for a maximum of forty-eight (48) hours.

SECTION 6. Tennessee Code Annotated, Section 53-10-305, is amended by deleting the section in its entirety and substituting instead the following:

53-10-305.

(a) All prescribers with DEA numbers who prescribe controlled substances and dispensers in practice providing direct care to patients in Tennessee for more than fifteen (15) calendar days per year shall be registered in the controlled substance database. New licensees shall have up to thirty (30) calendar days after notification of licensure to register in the database. Licensed veterinarians who never prescribe a controlled substance in an amount intended to treat a non-human patient for more than forty-eight (48) hours shall not be required to register in the database.

(b)

(1) Each dispenser or dispenser's agent shall, regarding each controlled substance dispensed, submit to the database all of the following information:

- (A) Prescriber identifier;
- (B) Dispensing date of controlled substance;
- (C) Patient identifier;
- (D) Controlled substance dispensed identifier;
- (E) Quantity of controlled substance dispensed;
- (F) Strength of controlled substance dispensed;
- (G) Estimated days supply;
- (H) Dispenser identifier;
- (I) Date the prescription was issued by the prescriber;
- (J) Whether the prescription was new or a refill;
- (K) Source of payment; and
- (L) Other relevant information as required by rule.

(2) The information in the database, as required by subdivision (b)(1), shall be submitted by a procedure and in a format established by the committee, at least once every seven (7) days for all the controlled substances dispensed during the preceding seven (7) day period.

(c) The committee shall have the authority to shorten the length of time dispensers are required to submit to the database through the promulgation of rules pursuant to the Uniform Administrative Procedures Act, compiled in title 4, chapter 5. When the committee shortens the length of time dispensers are required to submit to the database, the department shall provide notice to all dispensers who are registered in the database at least sixty (60) days prior to the date in which the rule goes into effect. If the committee shortens the length of time which dispensers must submit information to the database, a dispenser may provide to the committee a written statement indicating why it creates a hardship for that dispenser to submit information within that time period, and the committee may grant an extension up to seven (7) days within which that dispenser must submit the information to the database. Such a hardship extension shall be valid for two (2) years and may be renewed by the committee upon request of the dispenser.

(d) Any dispenser, except veterinarian dispensers, that uses a computerized system to record information concerning the dispensing of controlled substances, shall submit the required information to the database utilizing nationally recognized pharmacy telecommunications format standards.

(e) The board shall maintain the database in an electronic file or by other means established by the committee in such a manner so as not to infringe on the legal use of controlled substances, and in such a manner as to facilitate use of the database by the committee for identification of:

(1) Prescribing and dispensing practices and patterns of prescribing and dispensing controlled substances; and

(2) Individuals, facilities or entities that receive prescriptions for controlled substances from prescribers, and who subsequently obtain dispensed controlled

substances from a dispenser in quantities or with a frequency inconsistent with generally recognized standards of dosage for that controlled substance, or by means of forged or otherwise false or altered prescriptions.

(f) The committee or a designee appointed by the committee shall review information in the database. If the committee or its designee determines from review that a prescriber or dispenser may have committed a violation of the law, the committee shall notify the entity responsible for licensure, regulation, or discipline of that prescriber or dispenser and shall supply information required by the entity for an investigation of the violation of the law that may have occurred.

(g)

(1) The committee shall by rule establish the electronic format in which the information required under this section shall be submitted to the database and shall allow for waiver of electronic reporting for individual dispensers for whom it would cause undue hardship as determined by the committee. The waiver may be valid for two (2) years from ratification by the committee.

(A) The committee may authorize a designee to initially approve a waiver subject to ratification by the committee.

(2) The committee shall ensure the database system records and shall maintain for reference:

(A) Identification of each person who requests or receives information from the database;

(B) The information provided to each person; and

(C) The date and time the information is requested or provided.

(h) The committee shall make rules to:

(1) Effectively enforce the limitations on access to the database as described in this part; and

(2) Establish standards and procedures to ensure accurate identification of individuals requesting information or receiving information from the database without a request.

SECTION 7. Tennessee Code Annotated, Section 53-10-306(a), is amended by deleting the language “persons, and in accordance with the limitations stated and rules promulgated pursuant to this part.” and substituting instead the language “persons in accordance with the limitations stated and rules promulgated pursuant to this part, or as otherwise provided for in §53-10-311:”.

SECTION 8. Tennessee Code Annotated, Section 53-10-306(a)(2), is amended by deleting the subdivision in its entirety and substituting instead the following:

(2) Authorized committee, board, or department of health personnel or any designee appointed by the committee engaged in analysis of controlled substances prescription information as a part of the assigned duties and responsibilities of their employment;

SECTION 9. Tennessee Code Annotated, Section 53-10-306(a)(3), is amended by deleting the subdivision in its entirety and substituting instead the following:

(3) A prescriber conducting medication history reviews who is actively involved in the care of the patient; a prescriber or supervising physician of the prescriber conducting a review of all medications dispensed by prescription attributed to that prescriber; or a prescriber having authority to prescribe or dispense controlled substances, to the extent the information relates specifically to a current or bona fide prospective patient of the prescriber, to whom the prescriber has prescribed or dispensed, is prescribing or dispensing, or considering prescribing or dispensing any controlled substance. Each authorized individual referenced under this subdivision shall have a separate identifiable authentication for access;

SECTION 10. Tennessee Code Annotated, Section 53-10-306(a)(4), is amended by deleting the subdivision in its entirety and substituting instead the following:

(4) A dispenser or pharmacist not authorized to dispense controlled substances conducting drug utilization or medication history reviews who is actively involved in the care of the patient; or a dispenser having authority to dispense controlled substances to the extent the information relates specifically to a current or a bona fide prospective patient to whom that dispenser has dispensed, is dispensing, or considering dispensing any controlled substance. Each authorized individual referenced under this subdivision shall have a separate identifiable authentication for access;

SECTION 11. Tennessee Code Annotated, Section 53-10-306(a)(6), is amended by adding the language “or violations under this part” after the language “controlled substances” and before the language “; and that any law”.

SECTION 12. Tennessee Code Annotated, Section 53-10-306(a)(6)(C), is amended by deleting the language “a law enforcement agency, a judicial drug task force or the TBI” and substituting instead the language “law enforcement personnel”.

SECTION 13. Tennessee Code Annotated, Section 53-10-306(a), is amended by adding the following language as a new appropriately designated subdivision ():

() A health care practitioner extender, who is acting under the direction and supervision of a prescriber or dispenser, and only to the extent the information relates specifically to a current or bona fide prospective patient to whom the prescriber or dispenser has prescribed or dispensed, is prescribing or dispensing, or considering prescribing or dispensing any controlled substance. Each authorized individual referenced under this subdivision shall have a separate identifiable authentication for access;

SECTION 14. Tennessee Code Annotated, Section 53-10-306(h), is amended by deleting the subsection in its entirety and substituting instead the following:

(h) Any prescriber, dispenser or health care practitioner extender receiving patient-specific information pursuant to subdivision (a)(1), (a)(2), (a)(3), or (a)(4) shall not disclose the information to any person other than:

(1) The patient to whom the information relates for the purpose of adjusting the patient's treatment plans or counseling the patient to seek substance abuse treatment;

(2) Other dispensers or prescribers who are involved or have a bona fide prospective involvement in the treatment of the patient, or dispensers or prescribers identified by the information for the purpose of verifying the accuracy of the information; or

(3) Any law enforcement personnel to whom reporting of controlled substances being obtained in a manner prohibited by §53-11-401, §53-11-402(a)(3) or (a)(6) and required by §53-11-309, or any agent of the prescriber who is directed by the prescriber to cause a report to law enforcement to be made in accordance with §53-11-309(a) and (d).

SECTION 15. Tennessee Code Annotated, Section 53-10-306(j)(4), is amended by deleting the subdivision in its entirety and substituting instead the following:

(4) The results of the audit conducted pursuant to subdivision (j)(2) shall be discoverable by a prescriber, dispenser or health care practitioner extender charged with violating any state or federal law involving controlled substances or under a notice of charges proffered by an appropriate licensing board for a violation of any law involving controlled substances, but only the results pertaining to that prescriber, dispenser or health care practitioner extender are discoverable. If, however, there is an active criminal investigation involving a prescriber, dispenser or health care practitioner extender or the prescriber, dispenser or health care practitioner extender is under investigation by any investigations or prosecution unit of the appropriate licensure board, the results of the audit conducted pursuant to subdivision (j)(2) shall not be discoverable by the prescriber, dispenser or health care practitioner extender during either such period.

SECTION 16. Tennessee Code Annotated, Section 53-10-307(d), is amended by deleting the subsection in its entirety and substituting instead the following:

(d) Submitting the information as required by this part shall not subject the person submitting the information to licensure disciplinary action or any action for breach of confidentiality, ethical duty to a patient, or the sharing of any professional secret.

SECTION 17. Tennessee Code Annotated, Section 53-10-308(a), is amended by deleting the subsection in its entirety and substituting instead the following:

(a)

(1) Notwithstanding any other provision of this part to the contrary, the committee or its designee, after consultation with the member of the committee who represents the board which has licensed the individual being considered for investigation, may release confidential information from the database regarding dispensers, prescribers, health care practitioner extenders, or patients, to a manager of any investigations or prosecution unit of an appropriate licensure board, committee, or other governing body that licenses or registers dispensers, prescribers or health care practitioner extenders and is engaged in an investigation, adjudication, or prosecution of a violation under any state or federal law that involves a controlled substance.

(2) Notwithstanding any other provision of this part to the contrary, the committee or its designee may release confidential information from the database regarding patients to law enforcement personnel engaged in an investigation, adjudication, or prosecution of a violation under any state or federal law that involves a controlled substance, pursuant to the procedure established in § 53-10-306(a)(6).

(3) Notwithstanding any other provision of this part to the contrary, the committee or its designee shall release information from the database when ordered by a court to do so upon the court's finding that disclosure is necessary for the conduct of proceedings before the court regarding the investigation, adjudication, or prosecution of a violation under any state or federal law that

involves controlled substances and after an appropriate protective order is issued regarding the information to be released to the court.

SECTION 18. Tennessee Code Annotated, Section 53-10-308(c), is amended by deleting the subsection in its entirety and substituting instead the following:

(c) No information may be released under this section until it has been reviewed by the committee or its designee and the member of the committee who represents the board which has licensed the individual being considered for investigation, and certified that further investigation or prosecution is warranted and that release of the information is necessary to that continued investigation or prosecution.

SECTION 19. Tennessee Code Annotated, Section 53-10-309, is amended by deleting the word “or pharmacist” and substituting instead the word “, dispenser or health care practitioner extender”.

SECTION 20. Tennessee Code Annotated, Section 53-10-310, is amended by deleting the section in its entirety and substituting instead the following:

53-10-310.

(a) Each person or entity operating a practice site where a controlled substance is prescribed or dispensed to a human patient shall provide for electronic access to the database at all times when a prescriber or dispenser provides health care services to a human patient potentially receiving a controlled substance.

(b) This section shall not apply to any dispensers that are not required to report pursuant to §53-10-304(d) or §53-10-305(g).

(c) A violation of subsection (a) is punishable by a civil penalty not to exceed one hundred dollars (\$100) per day assessed against the person or entity operating the practice site; provided, however, that the penalty shall only be imposed when there is a continued pattern or practice of not providing electronic access to the database.

(d) Any prescriber, dispenser, individual or entity who is authorized to access the database by this part shall not be subject to a suit for civil damages or held civilly liable for the failure to register in, report to, or check the database, or for actions taken after

reasonable reliance on information in the database, or accessing the database to determine whether or not the prescriber or dispenser's professional medical credentials are being inappropriately used or for reporting the same to the appropriate authorities, except as otherwise provided in this.

(e)

(1) All prescribers or their designated health care practitioner's extenders, unless otherwise exempted under this part, shall check the controlled substance database prior to prescribing one of the controlled substances identified in subdivision (e)(3) to a human patient at the beginning of a new episode of treatment and shall check the controlled substance database for that human patient at least annually when that prescribed controlled substance remains part of the treatment.

(2) Before dispensing, a dispenser shall have the professional responsibility to check the database or have a health care practitioner extender check the database if the dispenser is aware or reasonably certain that a person is attempting to obtain a Schedule II-V controlled substance, identified by the committee as demonstrating a potential for abuse for fraudulent, illegal, or medically inappropriate purposes, in violation of §53-11-402.

(3) The controlled substances which trigger a check of the controlled substance database pursuant to subdivision (e)(1) include, but are not limited to, all opioids and benzodiazepines. By rule, the committee may require a check of the database for additional Schedule II-V controlled substances that are identified by the committee as demonstrating a potential for abuse.

(4) The board shall adopt rules in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, that establish standards and procedures to be followed by a dispenser regarding the review of patient information available through the database.

(5) Prescribers are not required to check the controlled substance database before prescribing or dispensing one of the controlled substance identified in subdivision (e)(3) or added to that list by the committee if one or more of the following conditions is met:

(A) The controlled substance is prescribed or dispensed for a patient who is currently receiving hospice care;

(B) The committee has determined that prescribers in a particular medical specialty shall not be required to check the database as a result of the low potential for abuse by patients receiving treatment in that medical specialty;

(C) The controlled substance is prescribed or dispensed to a patient as a non-refillable prescription as part of treatment for a surgical procedure that occurred in a licensed health care facility.

(D) The quantity of the controlled substance which is prescribed or dispensed does not exceed an amount which is adequate for a single, seven (7) day treatment period and does not allow a refill.

(f) Each appropriate licensure board shall promulgate rules pursuant to the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, to establish procedures, notice requirements, and penalties for prescribers and dispensers who fail to register in, report to, or check the controlled substance database as required.

(g) Notwithstanding any other provision of this part to the contrary, a prescriber, dispenser or health care practitioner extender shall not be in violation of this part during any time period in which the controlled substance database is suspended or not operational or the Internet is not operational or available as defined by rules promulgated by the commissioner after consultation with the committee.

SECTION 21. Tennessee Code Annotated, Title 53, Chapter 10, Part 3, is amended by adding the following as a new section:

53-10-311.

Notwithstanding any other provision of this part to the contrary, the commissioner is authorized to enter into agreements with other states or other entities acting on behalf of a state for the purposes of sharing and dissemination of data and information in the database. Disclosure of such agreements shall be consistent with the provisions and limitations set forth in this part. All such agreements shall specifically provide which prescribers, dispensers, health care practitioner extenders or law enforcement personnel who are licensed, registered, or certified in other states shall have access to the database.

SECTION 22. Tennessee Code Annotated, Section 53-11-309(a), is amended by adding the word "pharmacist," after the word "veterinarian," and before the word "advanced".

SECTION 23. Tennessee Code Annotated, Section 53-11-402(b)(1), is amended by deleting the subdivision in its entirety and substituting instead the following:

(b)

(1) A violation of this section is a Class D felony, except that a violation of subdivision (a)(6) is a Class A misdemeanor and any violation of subdivision (a)(6) involving more than two hundred fifty (250) units of a controlled substance is a Class E felony. For purposes of this subdivision, a "unit" means an amount of a controlled substance in any form that would equate to the initial single individual dosage recommended by the manufacturer of the controlled substance.

SECTION 24. Tennessee Code Annotated, Section 63-1-309(c), is amended by deleting the subsection in its entirety and substituting instead the following:

(c) If any practitioner providing services at a pain management clinic dispenses or prescribes controlled substances for the treatment of chronic nonmalignant pain, the practitioner must document in the patient's record the reason for prescribing or dispensing that quantity.

SECTION 25. This Act shall be interpreted to be consistent with all state and federal laws addressing privacy of patient records.

SECTION 26. Tennessee Code Annotated, Section 53-10-309, is amended by adding the following language between the first and second sentences of that section:

The committee's annual report shall include information about the prescribing and dispensing patterns of prescribers and dispensers, and this data shall be made available electronically to prescribers and dispensers in a format that will allow them to compare their prescribing and dispensing patterns to those of their peers.

SECTION 27. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to that end the provisions of this act are declared to be severable.

SECTION 28. For purposes of promulgating rules and regulations, including emergency rulemaking, this act shall take effect upon becoming law, the public welfare requiring it. For all other purposes, except the requirements of subdivision (e)(1) in Section 20, this act shall take effect on January 1, 2013, the public welfare requiring it. The requirements of subdivision (e)(1) in Section 20 shall take effect on April 1, 2013, the public welfare requiring it. The provisions of this act shall expire and be of no force and effect after June 30, 2016 and on July 1, 2016, the existing provisions of Tennessee Code Annotated, Title 53, Chapter 10, Part 3, shall be revived and reenacted as they were codified on March 1, 2012.